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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,483	03/29/2004	Jun Liu	146392005600	5594

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EXAMINER	
KIM, YUNSOO	
ART UNIT	PAPER NUMBER
1644	
MAIL DATE	DELIVERY MODE
07/02/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/813,483	LIU ET AL.	
	Examiner	Art Unit	
	YUNSOO KIM	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-8,20,22-25,51 and 52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-8,20,22-25,51 and 52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/28/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1, 4-8, 20, 22-25, 51 and 52 are pending and under consideration.

2. Applicants' IDS filed on 4/28/10 has been acknowledged.

3. The following rejections remain.

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1, 4-8, 20, 22-25, 51 and 52 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 7-13, 22-27, 31-34, 37-42, 48, 51-56, 58 and 59 of U.S. Patent No. 6,875,432 B2, of record, in view of US 2004/109243A1, of record, for the reasons set forth in the office action mailed on 10/27/09.

Applicant's responses filed on 4/28/10 have been fully considered but they were not persuasive.

Applicant has asserted the patent claims and the claims of the instant application do not have overlapping concentration of the antibody (about 130mg/ml vs. about 150mg/ml) and pH. Applicant has further argued that the dependent claims 19 and 20 require reconstitution from lyophilized formulation. Applicant has asserted that the use of specification as a prior art is prohibited if a claim of an application is an obvious variation. Further, Applicant has stated that no specific combinations of excipients are disclosed in the '432 patent.

As discussed previously, the claims of the '432 patent recite acid, base and/or buffer at 150mM-200mM (claims 32-34) which encompass arginine-HCl (claim 8) and the pH range of "about 4.2-5.3 or about 6.3-12.0" (claim 31) wherein the claimed antibody encompasses rhuMab-E25 (claims 55, 56). Furthermore, the recitation of the amount of antibody being about 80 to about 130 mg/ml as in claim 1 is interpreted to encompass the antibody amount of 160-260mg/ml because of claim 20 of the '432 patent. Claim 20 of the '432 patent recites the claimed composition is lyophilized and reconstituted and the concentration of the reconstituted formulation is 2-40 times greater than protein concentration before lyophilization. Therefore, the antibody amount of the '432 patent encompasses a higher antibody amount than the antibody amount in claim 1 of the '432 patent.

Note the term "about" is considered clear but flexible (MPEP 2173.05 (b)). As Applicants assert, the term about is defined to mean "approximately", "nearly", or "more or less". The "more" end of patented about 130mg/ml overlap with the "lower" end of "about 150mg/ml" of the instant application. MPEP 2144.05 acknowledges that the prima facie obviousness exists where the claimed ranges and the prior art do not overlap but close enough that one skilled in the art would have expected to have the same property (MPEP 2144.05).

Note that the rejection was made in the presence of the secondary reference and the specific concentrations of are taught by the '243 publication.

Further, the independent claim 1 of the '432 patent is silent about lyophilization or reconstitution. Therefore, claim 1 of the '432 patent reciting "about 130mg/ml" is subject to lyophilization considering as a starting concentration and may be reconstituted. Note the specification of the '432 patent discloses that the reconstituted concentration of the antibody ranges "about 80mg/ml to about 300mg/ml" (col. 26, lines 45-50). Given that the reconstituted formulation is 2-40 times higher than before lyophilization, the resulted concentration encompasses "about 260mg/ml" especially in light of the teachings of the specification of the '432 patent (col. 26, liens 45-50). Thus, Applicants' assertion of the concentration of the antibody of claim 1 is "post-lyophilization" resulted from the reconstitution is misleading.

However, the specification may be considered when the portions of specification provides support for the patent claims when addressing the issue of whether the claim in the application defines obvious variation of an invention claimed in the patent. See MPEP 804.
In this case, the disclosure of the '432 patent (col. 26, lines 43-62) provides supports the obvious variations or optimization.

As discussed previously, both claim sets encompass an antibody formulation comprising rhuMab-E25 at 120-260mg/ml in arginine-HCl, histidine, polysorbate at pH of 5.5-6.0.

The claims of the '432 patent differs from the claims of the instant application in that they do not recite particular concentration ranges of histidine, arginine and polysorbate.

The '243 publication teaches a particular range of histidine being 10-50mM, arginine-HCl being about 60mM and the polysorbate at 0.01 to 0.1% (Table 5, [0094-0105], in

particular) and it is well known in the art that addition of arginine in combination of histidine decreases viscosity ([105], in particular).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the concentration ranges of the components of the stabilizing formulation as taught by the '243 publication in the stabilizing formulation comprising a buffer comprising histidine, arginine and polysorbate as taught by the '432 patent.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because the known concentration ranges of the '243 publication reduce undue optimization the stabilizing formulation while reducing solution viscosity.

For the reasons set forth above, the nonstatutory obviousness-type double patenting rejection is maintained.

6. Claims 1, 4-8, 20, 22-25, 51 and 52 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of copending Application No. 12/197,005 for the reasons set forth in the office action mailed on 10/27/09.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim sets recite a stable liquid antibody formulation comprising rhuMab-E25, arginine-HCl at 100-200mM, histine at 10-100mM, polysorbate at 0.01to 0.1% at pH 5.5 wherein a kinematic viscosity is about 50cs or less and an osmolarity ranging from 200mOsm/kg to 450mOsm/kg. Given that both claim sets recite the same formulation, the absorbance measurement using HP spectrophotometer as recited in claim 1 of the instant application is inherent property of the formulation comprising rhuMab-E25, arginine-HCl at 100-200mM, histidine at 10-100mM, polysorbate at 0.01to 0.1% at pH 5.5.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

As Applicant has requested that this double patenting rejection be held in abeyance until patentable subject matter has been identified in the instant application, the double patenting rejection is maintained.

7. No claims are allowable.

8. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to YUNSOO KIM whose telephone number is (571)272-3176. The examiner can normally be reached on M-F, 9-5. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Yunsoo Kim
Patent Examiner
Technology Center 1600
June 25, 2010

/Michael Szperka/
Primary Examiner, Art Unit 1644